



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,162	08/26/2003	Raymond E. Ideker	5656-33	3541
7590	02/23/2006		EXAMINER BERTRAM, ERIC D	
Laura M. Kelley Myers Bigel Sibley & Sajovec, P.A. P. O. Box 37428 Raleigh, NC 27627			ART UNIT 3766	PAPER NUMBER

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/648,162	Applicant(s) IDEKER, RAYMOND E.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/27/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 8/27/2003 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the margins are not correct and numbers, reference characters and figure legends are poor, as indicated in the attached Draftperson's Patent Drawing Review. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Art Unit: 3766

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-3, 5-11, 13-20, 22-26, 28-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Christini et al. (US 6,915,156). Christini et al. disclose a method and system for detecting and stabilizing discordant alternans that first chronically detects electrical activity in first and second regions of the heart using multiple internally implantable electrodes (Col. 5, lines 59-65 and Col. 6, lines 21-25). Christini et al. further describe the identification of repolarization alternans in the detected electrical activity by beat-to-beat (cycle-to-cycle) variations, as well as comparing amplitudes (Col. 5, line 65-Col. 6, line 13). Repolarization alternans (RPA) is defined by Christini et al. as action potentials in different regions of the heart changing from concordant to discordant alternation (Col. 2, lines 6-9). As the name suggests, the condition specifically deals with alternation in the repolarization of the heart (i.e. the STT segment) and the T wave (Col. 2, lines 3-5 and 18-21). Christini et al. further discloses that RPA appears as a beat-to-beat alternation in amplitude, shape and/or duration of the T-wave (Col. 2, lines 21-23). While Christini et al. is silent as to what identifies RPA, there must inherently exist a RPA monitor at 135 that indicates to the operator the presence of RPA (Col. 6, lines 17-19). Responsive to the identification of RPA, Christini et al. teach the initiation of interventional therapy, the therapy consisting of an electrical stimulus (shock) or electrical stimuli (pacing) applied by the electrodes to stabilize a

Art Unit: 3766

target rhythm (Col. 6, lines 56-67). The therapy, which can be given in the atria (Col. 7, lines 7-9), further helps to prevent the onset of a ventricular arrhythmia (Col. 3, lines 7-10).

5. Regarding claim 13, Christini et al. disclose that it is old and well known in the art to use external electrodes to capture ECG signals for alternans detection (Col. 2, lines 27-30).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christini et al. ('156) in view of Pastore et al. (US 6,965,797). Christini et al., as described above, disclose the applicant's basic invention with the exception of using alternations in an activation recovery interval (ARI) to identify discordant alternans. Attention is directed to the secondary reference of Pastore et al., which teaches the

Art Unit: 3766

activation recovery interval of heart tissue may be used to identify pulse alternans, of which discordant alternans may be included. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method and system of Christini et al. by using ARI to identify discordant alternans since this is a known method of determining the existence of alternans in the heart.

9. Claims 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christini et al. ('156) in view of Norris et al. (US 6,823,213). Christini et al., as described above, disclose the applicant's basic invention with the exception of the interventional therapy comprising administering a drug upon detection of RPA.

Attention is directed to the secondary reference of Norris et al., which discloses that upon detecting alternans, a drug is dispensed from an implanted pump (Col. 3, lines 44-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method and system of Cristini et al. by adding the interventional drug therapy in order to treat acute and long-term risks (Col. 3, line 50).

10. Claims 38-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christini et al. ('156) in view of Pastore et al. ('797) and Norris et al. ('213). Christini et al, as modified above, disclose a method and apparatus completing all of the instructions contained in claims 1-17. Christini et al. does not, however, specifically disclose the use of a computer-readable medium loaded with code containing the instructions. Although Christini et al. does not disclose the medium, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to

Art Unit: 3766

include the medium since the use of a processor to complete identification and treatment of heart problems is old in the art, as shown in figure 1 of Pastore et al., and it is further known that a processor cannot function without first being programmed by a medium containing the necessary instructions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Eric D. Bertram
Examiner
Art Unit 3766